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-- PATENT APPLICATION --
-- Attorney Docket No. 25,835.11 --

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: M. L. Collins, et al.

Serial No.: 08/238,080

Filing Date: May 3, 1994

Title: TARGET AND BACKGROUND CAPTURE
METHODS WITH AMPLIFICATION FOR
AFFINITY ASSAYS

Art Unit: 1807

Examiner: Dianne Rees

CERTIFICATE OF MAILING & FACSIMILE RESPONSE

I hereby certify that this correspondence is being sent via facsimile to: Dianne Rees, at facsimile number (703) 305-7401, and is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: The Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date shown below.

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May 27, 1997

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AMENDMENT AFTER FINAL REJECTION

The Assistant Commissioner for Patents
Washington, D.C. 20231

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Dear Sir:

Please amend the above-captioned application as follows:

In the Claims:

Please cancel claims 51-52.

Please amend claims 53-54 as follows:

2 53. (Amended) A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of:

- (a) contacting the sample medium with reagent comprising a first nucleic acid probe which binds to the target to form a probe-target complex;
- (b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;

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- (c) substantially separating the support and bound probe-target complex from the sample medium;
- (d) contacting the support and bound probe-target complex with a second medium;
- (e) releasing the probe-target complex into the second medium;
- (f) substantially separating the support from the second medium; and
- (g) amplifying the target polynucleotide.

28 54. (Amended) A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:

- (a) contacting the sample medium with reagent comprising a first nucleic acid probe which binds to the target to form a probe-target complex;
- (b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;
- (c) substantially separating the support and bound probe-target complex from the sample medium;
- (d) contacting the support and bound probe-target complex with a second medium;
- (e) releasing the probe-target complex into the second medium;
- (f) substantially separating the support from the second medium;
- (g) amplifying the target polynucleotide; and
- (h) detecting the presence of the target polynucleotide.

Please add new claims 55-66 as follows:

29 55. The method for detecting a target polynucleotide of claim 29 wherein the target polynucleotide is amplified with a polymerase.

30 56. The method for detecting a target polynucleotide of claim 29 wherein the polymerase is a DNA polymerase, an RNA polymerase, a transcriptase, or Q β replicase.

31 57. The method for detecting a target polynucleotide of claim 30 wherein the polymerase is a DNA polymerase.

32 ~~58~~²⁷. The method for amplifying a target polynucleotide of claim ~~58~~ wherein the target polynucleotide is amplified with a polymerase.

33 ~~59~~³². The method for amplifying a target polynucleotide of claim ~~58~~ wherein the polymerase is a DNA polymerase.

34 ~~60~~. A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of :

- (a) contacting the sample medium with a support and a probe which binds to the target polynucleotide and the support;
- (b) substantially separating the support and bound probe and target polynucleotide from the sample medium;
- (c) contacting the support and bound probe and target polynucleotide with a second medium;
- (d) releasing the target polynucleotide into the second medium;
- (e) substantially separating the support and bound probe from the second medium; and
- (f) amplifying the target polynucleotide.

35 ~~61~~³⁴. The method for amplifying a target polynucleotide of claim ~~60~~ wherein the target polynucleotide is amplified with a polymerase.

36 ~~62~~³⁵. The method for amplifying a target polynucleotide of claim ~~61~~ wherein the polymerase is a DNA polymerase, an RNA polymerase, a transcriptase or Q β replicase.

37 ~~63~~³⁶. The method for amplifying a target polynucleotide of claim ~~62~~ wherein the polymerase is a DNA polymerase.

38 ~~64~~³⁷. A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:

- (a) contacting the sample medium with a support and probe which binds to the target polynucleotide and the support;

- (b) substantially separating the support and bound probe and target polynucleotide from the sample medium;
- (c) contacting the support and bound probe and target polynucleotide with a second medium;
- (d) releasing the target polynucleotide into the second medium;
- (e) substantially separating the support and bound probe from the second medium;
- (f) amplifying the target polynucleotide; and
- (g) detecting the presence of the amplified target polynucleotide.

38
39 65. The method for detecting a target polynucleotide of claim 64 wherein the target polynucleotide is amplified with a polymerase.

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40 66. The method for detecting a target polynucleotide of claim 65 wherein the polymerase is a DNA polymerase.

REMARKS

Applicants wish to express their appreciation for the courtesy extended by the Examiner to Applicants' representative in telephonic interviews March 26 and April 7, the Examiner's consideration of the Draft Amendment After Final Rejection submitted April 16, the Examiner's consideration of the art references submitted April 17 (and resubmitted April 25), and the Examiner's brief discussion of the Draft Amendment and art references with Applicant's representative on April 30. (The interviews are summarized in the Interview Summaries dispatched by the Examiner on April 8.) Applicants submit these communications have proven useful: Although agreement has not been reached with respect to all claims, the Examiner has indicated that claims 53 and 54 as amended herein and new claims 55-66 are patentable.

Claims 25-54 are pending in the application. All pending claims stand rejected in an Office Action mailed January 17, 1997 and the rejection has been made final. Claims 51-54 are rejected under 35 USC § 112, second paragraph as indefinite. Claim 51 is rejected for its

recitation of the phrase "a second medium". Claim 51 depends from claim 27 and, as the Examiner notes, claim 27 does not recite a "first medium". Accordingly, claim 27 provides no context for a "second medium". The Examiner further asserts that it is unclear what the metes and bounds of the term "medium" are.

Claims 25-42, 44 and 48-50 are rejected under 35 USC §103(a) as unpatentable over Vary et al in view of Hanson. Claims 25-50 are rejected under 35 USC §103(a) as unpatentable over Vary in view of Hanson and further in view of Rabbani. Claims 51-54 are rejected under 35 USC 103(a) as unpatentable over Vary et al in view of Hanson. Applicants traverse the rejections and have filed a Notice of Appeal to appeal certain of these rejections.

However, as the Examiner has indicated that claims 53-54 as amended herein and new claims 55-66 are patentable, entry of the Amendment will remove claims 51-54 from consideration in the appeal. Thus, entry of the amendment will advance those claims toward allowance and simplify the issues to be considered on appeal. Accordingly, Applicants request entry of the Amendment.

The Amendment amends pending claims 53-54 and adds new claims 55-66. Applicants submit and the Examiner has agreed that the amendment overcomes the rejections to pending claims 51-54.

